Pending Claims and Amendments

Prior to amendment, claims 1-99 were pending in this application. Claims 1-4, 7-43, 51-52, 59-65, 67, 69-70, 75-86, and 92-93 have been canceled. Claims 5, 6, 44, 47, 50, 53-58, 66, 68, 87-89, 94-97 and 99 have been amended. New claims 100-123 have been added. Thus claims 5, 6, 44-50, 53-58, 66, 68, 71-74, 87-91, 94-123, are currently pending in this application.

I. Claim Rejections – 35 USC § 101

Claims 92-99 stand rejected under 35 U.S.C. 101. Examiner states:

... the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, ... renders these claims non-statutory.

Claims 94-99 have been amended to clarify the intended claim language, i.e., to read "...providing at least one electrode and coupling the at least one electrode to tissue..."

II. Claim Rejections – 35 USC § 102

A. Rejections Based on Scheiner

Claims 1-5, 9-18, 20-25, 27, 51-53, 55-57, 59, 61, 64-66, 68-73, 92-94 and 96-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner et al. (US 6,415,183). Examiner states:

> Scheiner et al. discloses a diaphragmatic pacing system, which monitors respiratory activity and stimulates the phrenic nerve when respiratory activity is below a certain level.
>
> As to claims 1-4, 59, 71-72 and 92, in figure 1, the "tip electrode 121 and ring electrode 122 can be used for sensing respiratory activity by a method such as minute ventilation, as will be explained below, and/or for delivering diaphragm therapy by delivering an electric stimulus to phrenic nerve 102(col. 3, 38-43), which controls the patient's diaphragm. " Electrodes 121 and 122 of first lead 120 are coupled to inputs 181 and 182 on a device 170" (col. 3, 32-34). The examiner considers the device 170, to be the responsive device and the electrodes 121 and 122 to be sensors as well since they have the capability of sensing and stimulating.

As to claims 5, 57, 73 and 98, Scheiner et al. discloses in col.5, lines 44-45, the use of the patient's minute ventilation as a physiological state. The minute ventilation is the amount of new atmospheric air that has moved into the respiratory passages each minute (Hole's Human Anatomy and Physiology, pg 798). (Please see Reference U) Therefore, since the minute ventilation is the amount of new air taken into the lungs, the examiner considers that to inherently be the inspiration rate over a one-minute time interval.

As to claims 9-10, the electrodes sense a signal, which "represents a physiological state, such as respiratory activity. The state can be a patient's minute ventilation, for example. Alternatively, it could be chest wall motion" (col. 6, lines 53-56). Since the device can detect chest wall motion, it inherently has a movement detector for detecting the expansion and contraction of the chest. The expansion and contraction of the chest is directly related to the movement of the diaphragm.

As to claims 11, 16, 20-21, 61 and 64-66, "the present system is applicable for treating respiratory ailments such as sleep apnea. The system provides for sensing a physiological state of the patient related to respiration effort using an electrode implanted in the heart. When a physiological state indicating a need for therapy is detected, an electrical stimulus is triggered by a controller, and the electrode delivers an electric stimulus to the phrenic nerve, initiating a respiratory cycle. In another embodiment, when a physiological state indicating a respiratory event is detected, the controller inhibits delivery of an electrical stimulus, which is programmed to be delivered at a predetermined rate"(col. 1 and 2, lines 65-67 and 1-9).

As to claims 17-18 and 68-70, the need for therapy arises when the respiratory rate falls below a threshold or predetermined rate. "For example (in figure 3), if the present system is used to alleviate apnea, block 302 can be set so that if the minute ventilation goes below a preselected apneic threshold set by the physician, such as 5 liters/minute, then the method goes to block 303" (col. 6, lines 61-65). According to the Applicant's specification, "hypoventilation is a condition in which the respiratory rate is pathologically low or below a desired rate"(page 1, lines 25-27). Therefore, since Scheiner et al. senses when respiration rate falls below a threshold or predetermined rate, Scheiner et al. inherently detects hypoventilation.

As to claims 22-25 and 27, the "controller 224 includes one or more microprocessors and logic circuits for execution of software or firmware instructions. The software of controller 224 is modifiable to provide different functions"(col. 6, lines 47). The "controller 224 can also be externally programmed" (col. 6, line 24). Figure 10 is a view of the implanted programmable pacing system. The disclosure and the drawings of Scheiner et al. refers to figure 8 as the programmable pacing system. However, the figure is actually figure 10. The examiner has inserted the reference numbers relating to figure 10. "FIG. 8 (10) shows an exemplary programmable controller system 800 (1000). System 800 (1000) is known in the art, and it includes an external programmer 801 (1001) having a transducer 802 (1002), which sends signals to controller 224 and other components in device 170. Using programmable controller system 800 (1000), a physician can change the operating mode of device 170 and controller 224. For example, it can be changed from

inhibited mode to triggered mode or asynchronous mode. Other details of operating modes will be described below"(col. 6, lines 24-33). Therefore, since the system is externally programmable the system inherently has a telemetry device for telemetric means.

As to claims 51, 53, 56, 94 and 97, "the method illustrated in FIG. 4 delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level"(col. 7, lines 55-58). "The minute ventilation is the product of respiration rate and tidal volume"(col. 5, lines 48-49). Since the minute volume is sensed and the minute volume is the product of respiration rate and tidal volume, both respiration rate and tidal volume are inherently sensed.

As to claims 52, 55, 93 and 96, in addition to the frequency being adjustable, the pulse amplitude and duration can also be modified. "It is contemplated that, considering the factors of electrode position and power conservation, the threshold voltage needed to stimulate the phrenic nerve will be an RMS constant voltage stimulus in the range between 0.2 volts to 14 volts with a pulse duration between approximately 0.2 milliseconds to 12 milliseconds. Alternatively, a physician can choose a constant current pulse having the same approximate energy range" (col. 4-5, lines 61-67 and 1).

Scheiner

Scheiner discloses stimulating the phrenic nerve to pace the diaphragm. Diaphragmatic pacing is defined within the Scheiner patent column 1, line 34 as "inducing a respiratory cycle." It discloses using frequent measurements of transthoracic impedance to estimate minute ventilation and accordingly "respiratory activity". Chest wall motion and intrathoracic pressure were also described as signals that may represent respiratory activity.

Claims 5, 57, 73 and 98.

Regarding claims 5, 57, 73, 98, the claims recite a responsive device configured to determine information corresponding to a patient's inspiration rate (claim 5); a programming device configured to adjust stimulation to adjust stimulation to control inspiration rate (claim 57); a method comprising electrically stimulating tissue to alter respiration to cause inspiration rate to approach a desired inspiration rate (claim 73); a method comprising a step of adjusting stimulation to control inspiration rate (claim 98). In the Examiner's rejection, Examiner has inappropriately considered the term "inspiration rate" as used and described in the present application to be synonymous with "respiration rate". Inspiration rate as used in

the current application is not synonymous with respiration rate. Respiration rate is the number of breaths in a given period of time. The present application uses inspiration rate as the speed of inspiration, i.e., as related to the slope of the inspiration portion of a respiration cycle. (See Page 8, lines 7-12, Page 18, lines 15-20, Figures 10A and 10B illustrating an increased inspiration rate with waveform 553 when the burst of pulses 563 is applied.) Accordingly, the elements regarding inspiration rate as claimed in claims 5, 57, 73 and 98 are not disclosed in Scheiner.

Examiner states that since the minute ventilation is the amount of new air taken into the lungs, the examiner considers that to inherently be the inspiration rate over a one-minute time interval. Minute ventilation is a product of the respiration rate and tidal volume. This is clearly set forth in Scheiner and is well known in the art. Examiner's reasoning is faulty and not based on what is clearly known in the art. The same amount of air can be taken in a given respiration cycle and yet have a different inspiration rate, i.e., inspiration rate is not necessarily related to minute ventilation or respiration rate. Scheiner does not recognize any significance of inspiration rate. Furthermore, Scheiner senses respiration over several respiration cycles (minute ventilation is volume over a period of one minute, i.e., over a period including several breaths) and thus Scheiner does not sense inspiration rate which is a breath by breath determination.

Finally, Scheiner only discusses pacing diaphragm in terms of inducing a respiratory cycle, not manipulating a respiratory cycle. Accordingly Applicant submits that claims 5, 57, 73, and 98 are not anticipated by Scheiner.

Claims 71-73

Claims 71-73 recite a method that includes sensing a characteristic of respiration, comparing it to a desired characteristic and then electrically stimulating tissue to alter respiration to cause a characteristic to approach the desired characteristic. Thus, the method as claimed includes a proportional control whereby after a comparison of a characteristic to a desired characteristic stimulation is provided that causes the characteristic to approach the value of the desired characteristic. Scheiner does not disclose this proportional control of stimulation.

Rather, Scheiner detects an absolute value threshold indicating the respiratory rate is below the absolute value. Stimulation is then just turned on. No proportional control is provided to bring the respiratory rate to approach a desired respiratory rate. In other words no approach to a desired rate is provided. Stimulation is either turned on or off in Scheiner. Accordingly Applicant submits that claims 5 and 73 are not anticipated by Scheiner.

Claim 66

Regarding claim 66, the claim recites sensing intrinsic breathing; then subsequently sensing information corresponding to respiration; and then sensing resumption of intrinsic breathing in a patient after stimulating the tissue and ceasing electrical stimulation after resumption of the intrinsic breathing is sensed. Scheiner does not disclose the step of sensing intrinsic breathing prior to sensing information corresponding to respiration. Rather, Scheiner discloses just sensing information corresponding to respiration, i.e., respiration rate and comparing it to a preset level. According to Scheiner, when respiration falls outside a preset level, stimulation is provided and respiration is analyzed as to whether the diaphragm responded to the stimulation. However, Scheiner does not disclose the additional first step of sensing intrinsic breathing (instead of having a preset level) prior to sensing the respiration rate. Accordingly Applicant submits that claim 66 is not anticipated by Scheiner.

Claims 53 and 94

.Scheiner discloses a single pulse for stimulating the phrenic nerve to cause a breath and not a burst of pulses as claimed. Further, Scheiner does not disclose adjusting the frequency of a signal to elicit a desired respiratory response. Examiner states that, Scheiner discloses, "the method illustrated in FIG. 4 delivers the stimulation pulse at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level." However, Scheiner does not disclose adjusting a signal frequency. Rather Scheiner discusses frequency in terms of breathing frequency. (See Scheiner Col. 7, lines 37-40) Furthermore, such frequency of breaths is predetermined and not disclosed as adjusted or adjustable to get a different response. Also, Scheiner discloses either stimulating or not. It does not stimulate if minute ventilation is above a certain value. Accordingly

Applicant submits that claims 53 and 94 are not anticipated by Scheiner.

Claims 56 and 97

Claims 56 and 97 claim a method or device where stimulation is adjusted to control tidal volume of a respiratory cycle. Scheiner does not disclose adjusting stimulation to control tidal volume of a respiratory cycle. The Examiner states, "The minute ventilation is the product of respiration rate and tidal volume" (col. 5, lines 48-49). Since the minute volume is sensed and the minute volume is the product of respiration rate and tidal volume, both respiration rate and tidal volume are inherently sensed."

While minute ventilation is described in Scheiner as being sensed or approximated using thoracic impedance and minute ventilation is known to be volume of air inhaled and exhaled during a period of time, nowhere does Scheiner disclose adjusting tidal volume of a particular respiration (or single breath) and such adjustment is not inherent when approximating minute ventilation. Applicants further note that Scheiner discloses using a single pulse to induce a respiratory cycle. Thus, no control is exerted on tidal volume, rather Scheiner is an on/off system. Accordingly, Applicant submits that claims 56 and 97 are not anticipated by Scheiner.

Claims 55 and 96

Claims 55 and 96 claim a device or method that adjusts pulse duration to elicit a desired response. Scheiner discloses a single pulse for stimulating the phrenic nerve to cause a breath and not a burst of pulses. Stimulating with a single pulse as opposed to a burst of pulses as claimed will not yield the same result. Furthermore, Scheiner does not disclose adjusting the pulse duration to elicit a desired respiratory response. While Scheiner discloses a possible range of pulse durations that could be used in the system it describes, it does not disclose adjusting the pulse duration during stimulation to elicit a desired response. Accordingly Applicant submits that claims 55 and 96 are not anticipated by Scheiner.

B. Rejections Based on Meer

Claims 1-5, 7-8, 11-16, 61-63 and 71-73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Meer (US 4,830,008). Examiner states:

> Meer discloses a method and treatment for sleep apnea by monitoring the diaphragm EMG and phrenic nerve activity and stimulates the upper airways accordingly.
>
> As to claims 1-5, 16, 61 and 71-73, figure 4 shows two effector electrodes 32, which "stimulate various muscles in the upper airway to maintain a patent upper airway simultaneously with stimulation of the diaphragm and other accessory muscles for inspiration such as the sternomastoid muscles to cause inspiration at a predetermined rate when no inspiratory effort is sensed by the monitor 14" (col. 4 and 5, lines 65-68 and 1-2). "The effector electrode 32 also serves as a second-sensor electrode" (col. 4, lines 41-42).
>
> As to claims 7 and 62, "inspiratory effort can be monitored by monitoring contraction of the diaphragm by electromyogram, sensing nerve conduction of the phrenic nerve, i.e. monitoring action potentials, monitoring intrathoracic pressure change via a pressure transducer, or by the use of an impedance pneumogram" (col. 5, lines 17-23). As to claims and 63, "the sensor electrode 24 is placed around the cervical portion of the phrenic nerve to detect action potentials in the phrenic nerve, i.e. incipient inspiration. The electrical signal generating mechanism 16 generates electrical signals based on information obtained from the phrenic nerve to maintain a patent airway in patients with obstructive sleep-apnea syndrome. In this arrangement, the electrical signal generating mechanism 16 may also act as a phrenic nerve stimulator in patients with central sleep-apnea syndrome"(col. 5, lines 17-23).
>
> As to claims 12 and 13, since Meer discloses sensing the phrenic nerve activity and diaphragm activity, the lack of signals from either the phrenic nerve or the diaphragm is also inherently sensed.
>
> As to claims 14 and 15, "the inspiratory effort monitored is analyzed by comparing the contraction of the patient's inspiratory muscles to a predetermined threshold contraction" (col. 2, lines 42-45). Since the threshold is preset, the phrenic nerve activity and the diaphragm are inherently compared with a preset value.

Meer

Meer discloses stimulating respiration in conjunction with stimulating the airway passages to open them up, purportedly to treat obstructive sleep apnea. Meer discloses on one hand sensing respiratory effort or inspiratory effort. Meer discloses stimulating the patient to open up air passageway when inspiratory effort crosses a predetermined threshold. The purpose of opening the air passageway is to prevent obstructive sleep apnea. Meer discloses on the other hand determining if there is an absence of inspiration in which case

central sleep apnea may be present.

Claims 5 and 73

Regarding claims 5 and 73, the claims recite a responsive device configured to determine information corresponding to a patient's inspiration rate (claim 5); and a method comprising electrically stimulating tissue to alter respiration to cause inspiration rate to approach a desired inspiration rate (claim 73). The present application uses inspiration rate as the speed of inspiration, i.e., as related to the slope of the inspiration portion of a respiration cycle. (See Page 8, lines 7-12, Page 18, lines 15-20, Figures 10A and 10B illustrating an increased inspiration rate with waveform 553 when the burst of pulses 563 is applied.) Meer does not disclose a responsive device configured to determine information corresponding to a patient's inspiration rate or a method whereby stimulation alters respiration to cause inspiration rate to approach a desired inspiration rate. Presence or absence of inspiration and/or inspiratory effort, are not equivalent to inspiration rate as set forth in the present application. Inspiration rate as used and set forth in the present application is not the same as respiratory rate or presence or absence of respiration of Meer. Examiner refers to Cols. 4 and 5 lines 65-68 and 1-2 of Meer which reads, "...stimulate various muscles in the upper airway to maintain a patent upper airway simultaneously with stimulation of the diaphragm and other accessory muscles for inspiration such as the sternomastoid muscles to cause inspiration at a predetermined rate when no inspiratory effort is sensed by the monitor 14" (col. 4 and 5, lines 65-68 and 1-2). Applicant believes that the use in Meer of the term "predetermined inspiration rate" refers to a predetermined number of breaths per period of time and that "rate" refers to the cycle rate of respiration. Meer uses respiration rate and inspiration rate interchangeably. There is no further description of inspiration rate in Meer and Meer does not refer to how fast or slow inspiration occurs or to the slope of the inspiration curve. Accordingly Applicant submits that claims 5 and 73 are not anticipated by Meer.

Claims 71-73

Claims 71-73 recite a method that includes sensing a characteristic of respiration, comparing

it to a desired characteristic and then electrically stimulating tissue to alter respiration to cause a characteristic to approach the desired characteristic. Thus, the method as claimed includes a proportional control whereby after a comparison of a characteristic to a desired characteristic stimulation is provided that causes the characteristic to approach the value of the desired characteristic. Meer, like Scheiner discussed above, does not disclose this proportional control of stimulation. Rather, Meer presence or absence of inspiration. Stimulation is then just turned on. No proportional control is provided to bring the respiratory rate to approach a desired respiratory rate. In other words no approach to a desired rate is provided. Stimulation is either turned on or off in Meer. Accordingly Applicant submits that claims 71-73 are not anticipated by Meer.

III. Claim Rejections – 35 USC § 103(a)

A. Rejections under Scheiner

Claims 6, 43-44,46-50, 54, 58, 74, 89-90, 91, 95 and 99 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 30-31,34-35,38, 60, 75-76, 78-80 and 86 above. Examiner states:

> The modified Scheiner et al. discloses the claimed invention except for sensing the expiration rate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the respiration rate as taught by the modified Scheiner et al. with the expiration rate since it was known in the art to sense the expiration and inspiration activity in order to diagnosis irregularities in normal breathing patterns.
>
> As to claims 44, 47 and 49-50, the modified Scheiner et al. discloses the claimed invention except for the tracking of patient activity compliance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the data stored and telemetrically sent to the physician since it was known in the art to report data to the physician in order to monitor the patient's condition and modify the treatment for patient for a distant location.
>
> As to claims 46 and 48, since information that could be sent to the physician could be patient compliance, which could be tracked by having a history stored in the memory. This physician could respond to this compliance with a change in treatment, either through stimulation modifications or pharmaceutical recommendations.
>
> As to claims 54 and 95, the modified Scheiner et al. discloses the claimed invention except for the adjustable pulse widths of the stimulation pulses. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation pulses as taught by the modified Scheiner et al. with adjustable pulse widths since it was known in the art to adjust the stimulation pulse parameters in order to modify treatment for individual patient's need.

Claims 6, 58, 74, 99

Regarding claims 6, 58, 74, 99 the Examiner states that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the respiration rate as taught by the modified Scheiner et al. with the expiration rate since it was known in the art to sense the expiration and inspiration activity in order to diagnosis irregularities in normal breathing patterns. " However, Examiner's statement does not apply to the claimed inventions. First the claims do not recite "modifying the respiration rate with the expiration rate." The respiration rate as set forth in the present application concerns respiration cycles in a given period of time whereas exhalation rate concerns the speed at which exhalation occurs as described in the specification.

Also, no basis is provided in the rejection for the statement that it is known in the art to sense expiration and inspiration activity in order to diagnose irregularities in normal breathing patterns. For example the rejection has not stated which irregularity and when would such activity be used for diagnosis and why would respiration rate and rate of expiration be interchangeable for such particular diagnosis. No cited references or art is provided that describe monitoring expiration to diagnose irregularities.

In any case, claim 6 claims a responsive device configured to determine information corresponding to exhalation rate; claim 58 recites adjusting stimulation to control exhalation rate; claim 74 recites stimulating to cause the exhalation rate to approach a desired characteristic; claim 99 recites adjusting stimulation to control exhalation rate. The rejection has not addressed why Examiner believes these particular claim elements are obvious. Such responsive device, control of exhalation rate, and stimulating to cause exhalation to approach a desired characteristic as claimed are not believed to be known in the art and are not disclosed in Scheiner.

Claims 44-46 and 50, 89-91

With respect to claims 44-46, and 50, Examiner is correct that Scheiner does not disclose tracking of patient activity compliance. However, the rejection of the claims does not address the claim element "patient activity compliance". Rather the rejection makes a general statement that it would be obvious to notify physicians of stored data. Scheiner does not, however, discuss storing, communicating or tracking any patient activity compliance, i.e. patient activity that complies with a regimen of treatment. Claims 46 and 91 further claim tracking or receiving a particular patient activity compliance, i.e., compliance with a drug regimen. This type of data is not stored, monitored or tracked by Scheiner. Examiner states, Applicants further submit that no teaching or suggestion is provided in Scheiner that would lead one of ordinary skill in the art to use an implantable sensor that senses information corresponding to respiration in combination with tracking patient compliance with treatment protocols, regimens or the like. Accordingly, Applicant submits that claims 44-46, 50 and 89-91 are not obvious from Scheiner.

Claims 47, 48

Claims 47-48 recite a device configured to recommend patient activity based on stored information. Scheiner does not disclose a device that senses information corresponding to respiration, in combination with recommending patient activity. And as further claimed in claim 48, Scheiner does not disclose recommending a drug regimen. Examiner's rejection states that a "...physician could respond to this compliance with a change in treatment, either through stimulation modifications or pharmaceutical recommendations." However, the claim recites that the device recommends treatment, not a physician in response to information sensed by the device. Accordingly, Applicant submits that claims 47 and 48 are not obvious from Scheiner.

Claims 54 and 95

Regarding claims 54 and 95, Examiner is correct that Scheiner does not disclose a programming device configured to adjust the pulse widths of a burst of pulses to elicit a desired respiratory response. Scheiner discloses a single pulse to initiate a respiratory cycle. Scheiner does not stimulate using a burst of pulses. The result of a single pulse is

different from a burst of pulses and thus it is not obvious from Scheiner to use a burst of pulses. In addition, Examiner does not explain how pulse width would be adjusted as applied in Scheiner and for what specific response or what the effect such modification would be. Scheiner does not disclose this or teach or suggest these details or such modification. Accordingly Applicant submits that claims 54 and 95 are not obvious in view of Scheiner.

B. Rejections under Scheiner in view of Clauson

Claims 26, 45 and 77 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner et al. (US 6,415,183), as applied to claims 6, 43-44, 46-50,54,58,74, 89-90, 91, and 99 above, in view of Clauson et al. (US 5,423,372). Examiner states:

> The modified Scheiner et al. discloses the claimed invention except for the patient communication and interface. Clauson et al. teaches that it is known to use a LCD display and keyboard. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the programming and interface as taught by the modified Scheiner et al. with LCD display and keyboard for inputting information as taught by Clauson et aI., in order to allow the patient to view their own data and utilize the keyboard to input information to the microprocessor.

Claim 45

As set forth above with respect to claims 44-46, 50 and 89-91, Scheiner does not teach or suggest tracking patient compliance. Clauson also does not teach or suggest tracking patient compliance. Claim 45 a patient interface configured to receive patient input concerning patient activity compliance. There is not teaching or suggestion of this element in either Clauson or Scheiner. Accordingly Applicant submits that claim 45 in not obvious from Scheiner in view of Clauson.

Conclusion

Applicant accordingly submits that claims 5, 6, 44-50, 53-58, 66, 68, 71-74, 87-91, 94-123 are patentable over the prior art relied on by Examiner and thus are in condition for allowance. An early and favorable action on the merits is respectfully requested.

Respectfully Submitted,

Dated: Susan M. Schmitt (Reg. No. 34,427)

PETERS, VERNY, JONES, SCHMITT & ASTON, LLP
425 Sherman Avenue, Suite 230
Palo Alto, CA 94306
Telephone: (650) 324-1677
Facsimile: (650) 324-1678
Customer No.: 23308